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EXAMINER	
LOUIE, MANDY C	

ART UNIT	PAPER NUMBER
1715	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,391	HIROSHI ET AL.	
	Examiner	Art Unit	
	MANDY C. LOUIE	1715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-4, 10, 16, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hevey [US 4234316] in view of Kloepfer [US 6696240] and Yamamoto [US 6846073].

As to claim 1, Hevey teaches a method for making an assay device (analytical tool) [col 1, ln 6] the method comprising a reagent member forming process for providing a base plate with a reagent member [col 2, ln 35-46] that includes a stack of at least two reagent layers separated by an intervening water soluble separation layer [col 2, ln 64-68; col 3, ln 1-3; Fig. 4], each of the reagent layers containing a reagent that reacts with a specific component contained in sample liquid [col 2, ln 44-45] and is different from a reagent contained in other reagent layer [col 7, ln 5-11], wherein the reagent layers separated by the intervening water soluble separation layer are aligned with each other in a direction perpendicular to the base plate [Fig. 4]. Although Hevey teaches the reagent member may be deposited via micropipetting (drop on demand

technique), the prior art is silent in teaching the reagent layers is formed by performing a plurality of steps of applying material liquid containing the reagent alternately with a plurality of steps of drying the applied material liquid. Kloepfer and Yamamoto remedy this.

In lieu of WO02/18144 publication in Japanese, US 20030179270 will used as an English translation, and hereafter be referred to in this office action for teachings of Yamamoto.

As to claim 1, Kloepfer teaches a general capillary test device comprising a reagent film [abstract] wherein the reagent film may be deposited by inkjet printing (drop on demand) [col 17, ln 53-57] and suggests that it would be desirable to increase the thickness of the reagent in order to maximize the sensitivity of the reagent member [col 15, ln 66-67; col 16, ln 1-2]. Yamamoto teaches a method for printing a thick film by inkjet printing (drop on demand) [0001], wherein the film may be formed by ejecting ink on a substrate and immediately curing the ink ejected [0009], and increasing the thickness by further ejecting ink onto the cured ink and immediately curing the ejected ink [0009]. Although Yamamoto teaches curing the UV ink to harden the ejected UV ink to prevent leveling [0010] rather than drying the ink, it would have been obvious to one of ordinary skill in the art that to solidify a liquid containing a reagent, one would dry the solution containing the reagent to leave a harden layer of reagent as taught by Hevey [col 3, ln 68].

It would have been obvious to one of ordinary skill in the art to modify the reagent member of Hevey to increase the thickness of the reagent layer, so as to maximize the

sensitivity of the reagent (Kloepfer, col 15, ln 66-67; col 16, ln 1-2), by performing a plurality of steps of applying the material liquid and alternatively with a plurality of steps of drying the applied material liquid (Yamamoto, 0009) since Yamamoto teaches the plurality of steps are operable to forming a thick film.

Regarding claim 2, in light of the prior art, the steps of applying and drying the liquid is performed with the same liquid so as to build a thicker layer [Yamamoto, 0008; 0010].

Regarding claim 3, in light of the prior art, the step of applying and drying are performed at least 2 times [Yamamoto, 0008; 0010].

As to claim 4, Hevey teaches the reagent content ranges from 5-98 wt%, (2-95% weight of binder, remainder constitutes the reagent) [col 3, ln 54-57], where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. (See MPEP 2144.05.I).

Regarding claim 10, in light of the prior art, the material liquid is applied to form each of the reagent layers with use of an inkjet type dispenser [Yamamoto, 0009].

Regarding claim 16, the prior art teaches it would be desirable to have a thicker reagent layer in order to maximize the sensitivity of the reagent layer [Kloepfer, col 15, ln 66-67; col 16, ln 1-2], wherein one of ordinary skill in the art would have optimize the final thickness of the reagent layer in order to achieve a desirable sensitivity. Although the prior art does not explicitly teach a thin film layer formed by performing one each of the applying step and drying step of the material liquid having a thickness of 0.1 to 5.0 micrometers, Yamamoto does teaches that the thickness of the film produced from the

first printing affects the predetermined final thickness of the desired final film [0099], wherein it would have been obvious to one of ordinary skill in the art to optimize the thickness of the thin film through routine experimentation, since the thickness of the thin layer would affect the number of times a thin layer would need to be produced in order to achieve the desired final film thickness. Moreover, it would have been innate to the teaching of the prior art that the final thickness of the reagent layer would be greater than each film to build the reagent layer.

As to claim 25, Hevey teaches the intervening water soluble separation layer is made of carboxymethylcellulose [col 3, ln11].

2. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hevey in view of Kloepfer, Yamamoto and Hevey [US 4387164] (hereinafter '164).

Teaching of the prior art is aforementioned, but appears to be silent in teaching the base plate comprises a reagent holding portion formed as a recess including a bottom surface and a side surface, and wherein the reagent member is formed in contact with the bottom surface. '164 remedies this.

As to claim 5, '164 teaches water soluble reagent members may be contained in a well that is attached to a reaction area defined by a depression within a surface [col 3, ln 25-57]; the well comprising a bottom surface and a side surface, wherein the reagent member is formed in contact with the bottom surface [i.e. Fig. 2].

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a container to house the reagent as taught by '164. One would have been motivated to do so to form a device that can be readily transported and

stored; protected and in stable form, and that only an aqueous medium need to be added to the well for analysis to be performed ['164, col 4, ln 38-45].

3. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hevey in view of Kloepfer, Yamamoto, '164 and Buechler [US 6113855].

Teaching of prior art is aforementioned, but appears to be silent in teaching the material liquid is applied to the bottom of the recess and spaced from the side surface by a constant distance, more specifically no smaller than 0.1 microns. Buechler remedies this.

Regarding claim 6, Hevey teaches the sample material to be analyzed is in liquid form [col 4, ln 47-49], Buechler teaches an assay device for fluid samples [abstract] wherein distance between structures would affect the capillary forces of a liquid sample being drawn into the assay device to be analyzed [col 2, ln 1-10]. Although Buechler does not explicitly teach the capillary inducing structures may be reagents, it would have been obvious to one of ordinary skill in the art to design the reagent member as a capillary inducing structure to improve the capillary force of drawing a sufficient amount of liquid sample into the reagent chamber for improved reaction results. Buechler further teaches the capillarity inducing structure may be substantially uniform [col 2, ln 66-67], which would suggest having uniform distance (space) between structures (i.e. reagent and side wall) so as to have better predictability of the capillary forces in action.

Regarding claim 7, Buechler teaches minute distances are required between opposing surfaces in order to achieve capillary forces [col 4, ln 15-17] wherein capillary spaces between 0.5 microns to 200 microns are useful for binding reaction to a solid

reactants [col 4, ln 63-64]. Hence, it would have been obvious to one of ordinary skill in the art that the distance between the reagent member and the side surface of the recess is a result effective variable on capillary forces.

It would have been obvious to one of ordinary skill in the art to modify or optimize the space around the reagent member to the side surface of the device. One would have been motivated to do so in order to improve fluid flow of the liquid sample to the reagent via capillary forces in order to improve the kinetics of the reaction [Buechler, col 4, ln 55-59].

2. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hevey in view of Kloepfer, Yamamoto, '164, and further in view of May [US 5089232].

Teaching of the prior art is aforementioned, but appears to be silent in teaching the recess (reagent holding portion) has a depth ranging from 50-200 micrometers (claim 8), where the recess has a volume ranging from 0.05-5 microliters (claim 9). May teaches these deficiencies.

Regarding claims 8-9, May teaches an apparatus for measuring the concentration of an analyte (i.e. vapor) [abstract], wherein the apparatus comprises channels that have cross sections in the reaction zone that is less than 10 microns squared [col 2, ln 29]; the channels further are coated with an indicator or reagent for detecting the analyte [col 3, ln 2-10]. May further teaches the reduced dimensions of the reagent holding portion improves sensitivity and detection of analyte in low quantities [col 2, ln 1-5]. Although May does not explicitly teach the reagent holding portion has the claimed depth or volume, it would have been obvious to one of ordinary skill in the

art to optimize the depth and volume of the reagent holding portion via experimentation as a result effective variable since such spatial dimensions (i.e. depth, width, length) would affect the sensitivity and detection of an analyte from a sample.

3. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hevey in view of Kloepfer and Yamamoto and further in view of Tisone [US 20020001675].

Teaching of the prior art is aforementioned, but appears to be silent in teaching the dispenser is designed to dispense the claimed range. Tisone remedies this.

Regarding claim 11, Tisone teaches a method for dispensing a reagent on a substrate [abstract] wherein the prior art teaches the size (volume) of the droplets will determine the effective resolution of the resulting pattern formed on the substrate [0075].

It would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the volume of the droplet dispensed via experimentation as a result effective variable so as control the resolution of the reagent pattern formed by the dispensed droplet; wherein Hevey teaches the size and shape of the reagent member affects how the liquid sample contacts the reagent member [col 2, ln 46-48]. It is further noted that the prior art teaches applying the material liquid to form each of the reagent layer by innately attaching a plurality of droplets to an application area to build a thicker film [Yamamoto, col 3, ln 5-20].

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hevey in view of Kloepfer and Yamamoto and further in view of Sasaki [US 20010055814].

A teaching of the prior art is aforementioned, but appears to be silent in teaching the amount of material liquid applied ranges from 1-200nL. Sasaki teaches this deficiency.

Regarding claim 12, Sasaki teaches in reagent dispensing environments, it is usually advantageous to dispense less than 100 nL [0031]. Sasaki also teaches it is possible to calibrate a printing device in order to deliver a predetermined amount of reagent required for an analytical device with a particular application [0030].

It would have been obvious to one with ordinary skill in the art at the time of the invention to modify the volume amount at which the material liquid is dispensed as taught by Sasaki. One would have been motivated to do so to effectively dispense a volume of reagent that is advantageous [Sasaki, 0031].

5. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hevey in view of Kloepfer and Yamamoto and further in view of Hashimoto [US 2003/0083203].

Teaching of the prior art is aforementioned, but appears to be silent in teaching some of the limitations of claims 13-15. Hashimoto remedies this.

Regarding claims 13-15, Hashimoto teaches a method for forming film patterns [title] with inkjet technique [abstract], where after droplets are dispensed onto the substrate, a drying treatment may be performed in order to remove a dispersion medium (solvent) with heat energy. The drying treatment may be with a common hot plate (holding a heat source with a rear surface of the base plate), or lamp annealing (heat applied by radiant heat from above) [0115].

It would have been obvious to one with ordinary skills in the art at the time of the invention to apply heat energy to dry the reagent layer with reasonable expectation of expediting the drying process of the liquid reagent. Moreover, it would have been obvious to one of ordinary skill in the art to either apply heat from above the reagent or from behind since both techniques would be operable in drying the reagent in a quicker fashion than of air drying.

Response to Arguments

4. Applicant's arguments with respect to claims 1-16, 25 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment, "water-soluble separation layer", wherein the arguments provided are directed to the newly added amendment.

Conclusion

1. No claim is allowed.

2. Claims 1-16, 25 are rejected for the reasons aforementioned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANDY C. LOUIE whose telephone number is (571)270-5353. The examiner can normally be reached on Monday to Friday, 7:30AM - 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on (571)272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. L./
Examiner, Art Unit 1715

/Timothy H Meeks/
Supervisory Patent Examiner, Art Unit 1715